

## REMARKS

### Status of the claims

Claims 1-50 are pending in the application. Claims 3, 6-8, 18, 26, 29-31, and 40-50 are withdrawn. Claims 1, 9, 12-17, 19, 24 and 32 are currently amended. Claims 8, 10-11, and 20 are canceled herein. Claims 1-2, 4-5, 7, 9-17, 19-25, 27-28, and 32-39 stand rejected. No new matter is added to these claims.

### Amendment to the claims

Claim 1 is amended to recite the limitations of a composition, comprised of at least one biomolecule, where the biomolecule is a biomaterial (instant specification pg 13, lines 21-23; pg 14, lines 1-3; pg 18, lines 14-15); and an electromagnetic energy absorbing species associated therewith, where the electromagnetic energy absorbing species is a susceptor (instant specification pg 18, lines 15-16), and where the susceptor is a metal (instant specification pg 18, lines 16-17); and where the metal absorbs electromagnetic energy (instant specification pg 20, lines 13-15), and where the electromagnetic energy absorbed is inductively applied (instant specification pg 1, lines 18-19, pg 18, lines 11-12, and pg 34, lines 14-15). Claims 9, 16, 19, 32, and 34 are amended to conform to the species election filed September 5, 2007. Claim 12 is amended to properly depend on claim 1. Claims 13-17 are amended to correct the claim preamble by incorporation of the word “composition” and deletion of the word “method”. Claim 24 is amended to recite the limitations of a composition comprised of at least one biomolecule, where the biomolecule is a biomaterial (instant specification pg 13, lines 21-23; pg 14, lines 1-3; pg 18, lines 14-15).

### Claim rejections under 35 U.S.C. §112

Claims 13-17, and 20 stand rejected under 35 USC 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-17 recite the preamble “method” rather than “composition”. Claim 20 reads like a method claim and the boundaries are confusing with regard to what the composition may or may not comprise. The method step of claim 20 applied to a

composition claim cannot be accorded much patentable weight. Applicant respectfully traverses the rejection.

Applicant amends the dependent claims 13-17 to recite the word “composition” and delete the word “method” to correct the claim preamble. Applicant cancels claim 20. Accordingly, in view of the arguments presented herein, Applicant respectfully requests the standing rejection of claims 13-17, and 20 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph be withdrawn.

#### Claim rejections under 35 U.S.C. §102

Claims 1, 9-10, 19-22, 24, 32, and 36-37 stand rejected under 35 U.S.C. §102(b) as anticipated by **Joyce** US Patent No: 4,558,690. Claims 1, 9-17, 19-21, 24, and 32-36 stand rejected under 35 U.S.C. §102(e) as anticipated by **Tachibana** et al, US Patent No: 6,332,095. Claims 1-2, 4-5, 9-10, 12-14, 19-21, 24, 27-28, 32, and 35-36 stand rejected under 35 U.S.C. §102(b) as anticipated by **Pandey** et al., US Patent No: 5,093,349. Applicant respectfully traverses the rejection.

In considering the **Joyce** reference, the Examiner argues claim 1 of the instant invention recites a biomolecule and an electromagnetic energy absorbing species associated therewith. **Joyce** discloses a cytotoxic agent encapsulated within a polymeric coating, which melts at an elevated temperature and melts with radiofrequency waves. Regarding claim 10, Applicant states the electromagnetic energy absorbing species is a susceptor, which is a material that may absorb electromagnetic radiofrequency energy. The susceptor has the ability to covert energy to heat. Thus, the Examiner argues **Joyce** anticipates the claimed invention by the fact that the tumor material in **Joyce** can comprise the electromagnetic energy absorbing species. Regarding claim 21, the Examiner argues the claimed change of state is anticipated by the melting of the coating, or tumor necrosis. Regarding claims 22 and 37, if the change of state is tumor necrosis, then this inherently involves denaturation, according to the Examiner.

Currently amended claim 1 recites a composition, comprising at least one biomolecule, where the biomolecule is a biomaterial; and an electromagnetic energy absorbing species associated therewith, and where the electromagnetic energy absorbing species is a susceptor, and where the susceptor is a metal; and where the metal absorbs electromagnetic energy, and where the electromagnetic energy absorbed is inductively applied. Currently amended claim 9 recites the composition of claim 1, where the biomolecule a biomaterial. Instant

claim 19 recites the composition of claim 1, where the electromagnetic energy absorbed is radiofrequency. Instant claim 21 recites the composition of claim 1, where the biomolecule, the electromagnetic energy absorbing species or both undergo a change in state upon application of electromagnetic energy to the composition. Instant claim 22 recites the composition of claim 21, where the change in state is a cleaved bond or denaturation. Instant claim 24 recites a composition, comprising at least one biomolecule, where the biomolecule is a biomaterial and a susceptor associated therewith. Currently amended instant claim 32 recites the composition of claim 24, where the biomolecule is a biologic, a biomaterial, or a diagnostic or a combination thereof. Instant claim 36 recites the composition of claim 24, where the biomolecule, the electromagnetic energy absorbing species, or both undergo a change in state upon application of electromagnetic energy to the composition. Instant claim 37 recites the composition of claim 36, where the change in state is a cleaved bond or denaturation.

Applicant submits that **Joyce** teaches a method of injecting a chemotherapeutic agent coated with a thermoplastic polymer having a melting point above normal body temperature (in a melting point range of about 40-46°C) accompanied dielectric radio-frequency localized heating of the tumor to elevate its interior temperature above the melting point of the encapsulating thermoplastic polymer (**Joyce Abstract**).

Applicant submits **Joyce** does not disclose a biomolecule that is biomaterial. **Joyce** does not teach the claimed invention without use of an encapsulating thermoplastic polymer coating. Nor does **Joyce** teach an electromagnetic energy absorbing species that is a susceptor, which is a metal. Further **Joyce** does not teach a metal that absorbs the electromagnetic energy, which is an applied magnetic field. Nor does **Joyce** teach the electromagnetic energy absorbed by the metal causes the metal to heat up by induction. As well **Joyce** does not disclose the use of heating temperatures that are greater than 50°C and more than 175-200W. Finally **Joyce** does not teach heating of the composition alone.

Applicant submits **Joyce** teaches use of microspheres of cytotoxic chemicals to tumor sites (**Joyce Abstract**). Further **Joyce** discloses a requirement for the chemotherapeutic agents to be coated with a thermoplastic polymer that has a melting point of 40-46°C (**Joyce Abstract**). As well, **Joyce** teaches injection of the polymer coated chemotherapeutic into the tumor site (**Joyce Abstract**). Therefore, **Joyce** teaches away from the instant specification, which discloses external application of the claimed invention. Furthermore, **Joyce** teaches the heating

of the tumor occurs by capacitive coupling of the energy to the tissue by means of capacitive plates positioned on either side of the injected and impregnated tumors. Thus **Joyce** the electromagnetic energy applied is electrical, and not magnetic as taught in the instant specification.

To anticipate the claimed invention, a prior art reference must recite each and every element, as set forth in the claim, that is, either expressly or inherently describe all the claim elements. **Joyce** does not meet this requirement for the currently amended claims. First, **Joyce** does not teach a biomolecule that is biomaterial, which is taught is any non-drug material (instant specification pg 14, line 1). Rather, **Joyce** teaches use of cytotoxic drugs that are chemotherapeutic chemicals. Second, **Joyce** does not teach use of a susceptor that is a metal. **Joyce** does not use a metal in their invention. Third, **Joyce** does not teach absorption of the applied electromagnetic energy by the metal susceptor. Rather **Joyce** teach use of a polymer coating that melts or tumor tissue that necroses. Fourth, **Joyce** does not teach the metal absorbs the electromagnetic energy by induction. Instead, **Joyce** teaches the heat is directly applied to the tumor tissue by capacitive coupling means. Fifth, **Joyce** does not teach heating the tissue greater than 200W or above 50°C, as taught in the instant specification (210W, pg 50 lines 13-16; and 55 °C, pg 19-20). These lower temperatures and lower wattages are not sufficient to be useful in the claimed invention, as taught in the instant specification.

Accordingly, in view of the arguments presented herein **Joyce** does not anticipate the instant invention and thus is not proper prior art. Therefore Applicant respectfully requests the standing rejection of claims 1, 9-10, 19-22, 24, 32, and 36-37 under 35 U.S.C. §102(b) be withdrawn.

Regarding the standing rejection of claims 1, 9-17, 19-21, 24, and 32-36 under 35 U.S.C. §102(e) as anticipated by **Tachibana** et al, US Patent No: 6,332,095, the Examiner argues that photosensitive substances can be combined with anti-tumor agents. Regarding claim 12, the Examiner argues that it is well known that fullerenes form dipoles.

Instant claims 1, 9-10, 19-21, 24, 32, and 36 are recited *supra*. Currently amended claim 12 recites the composition of claim 1, where the susceptor forms a dipole. Currently amended claim 13 recites the composition of claim 1, where the electromagnetic energy absorbing species comprises matter with non-zero electrical conductivity. Currently amended

claim 14 recites the composition of claim 13, where the matter is diamagnetic, paramagnetic, or ferromagnetic. Currently amended claim 15 recites the composition of claim 13, where the matter is an ionomer, a conducting polymer, an alkali metal, a transition metal, a lanthanide, or a metalloid or a combination thereof. Currently amended claim 16 recites the composition of claim 13, where the matter is stainless steel. Currently amended claim 17 recites the composition of claim 16, where the matter is a metal nano- or micro-particle, a semi-conducting nano- or micro-particle, a magnetic nano- or micro-particles, a polystyrene encapsulated metal particle, a buckminsterfullerene, or liposome encapsulated metal particles. Instant claim 33 recites the composition of claim 24, where the susceptor is a metal, a metal nano- or micro-particle, a semiconducting nano- or micro-particle, a magnetic nano- or micro-particles, a polystyrene encapsulated metal particle, a buckminsterfullerene, or liposome encapsulated metal particles. Instant claim 34 recites the composition of claim 33, where the metal is stainless steel. Instant claim 35 recites the composition of claim 24, where the susceptor forms a dipole.

Applicant submits **Tachibana** et al disclose a method of treating abnormal cells, including cancer cells, by administering a photosensitive chemical substance to accumulate at the cancer cell and applying a constant electric field to the abnormal cells to excite the photosensitive chemical to undergo a detrimental reaction to the abnormal cells (**Tachibana** et al, Abstract).

Applicant submits **Tachibana** et al do not disclose a biomolecule that is a biomaterial. Nor do **Tachibana** et al disclose an electromagnetic energy absorbing species that is a susceptor, which absorbs energy and avoids energy absorption in non-treatment areas. Further **Tachibana** et al do not teach the metal has magnetic properties. As well, **Tachibana** et al do not teach a metal as the susceptor to be heated by the applied energy. **Tachibana** et al do not disclose the use of heating temperatures that are greater than 50°C and more than 200W. **Tachibana** et al do not disclose treatment of the abnormal cells without use of a photosensitizing chemical substance. Nor do **Tachibana** et al disclose use of the treatment other than internal application.

Instead, **Tachibana** et al teach away from the instant invention by teaching the use of electrical fields generated by Tesla coils or a microwave generator, which excite the photosensitive material that is internally applied. As well, **Tachibana** et al teach away from the claimed invention by no use of heat or thermal events in the invention. Finally, **Tachibana** et al

teach away from the claimed invention by use of the photosensitive chemicals in conjunction with a chemotherapeutic drug.

Accordingly, in view of the arguments presented herein **Tachibana** et al do not anticipate the instant invention and thus is not proper prior art. Therefore Applicant respectfully requests the standing rejection of claims 1, 9-17, 19-21, 24, and 32-36 under 35 U.S.C. §102(e) be withdrawn.

Regarding the standing rejection of claims 1-2, 4-5, 9-10, 12-14, 19-21, 24, 27-28, 32, and 35-36 under 35 U.S.C. §102(b) as anticipated by **Pandey** et al., US Patent No: 5,093,349. Examiner argues **Pandey** et al describe a covalently bond target specific compound, such as ligand specific receptors, to the electromagnetic energy absorbing species of deuteroporphyrins, which may also be dimmers (dimer-bridging). Regarding claim 14, porphyrins are inherently magnetic.

Applicant submits **Pandey** et al disclose classes of photosensitizing compounds useful in photodynamic therapies. The compounds are dimmers and polymers of monohydroxy deuteroporphyrins, hydrophobic ethers of these monomers, and red light-absorbing derivatives of methyl pheophorbide-a (**Pandey** et al, Abstract).

Instant claims 1, 9, 12-17, 19-22, 24, and 32-37 are cited supra. Instant claim 2 recites composition of claim 1, where the biomolecule is associated with the electromagnetic energy absorbing species via a chemical linker. Instant claim 4 recites the composition of claim 1, where the biomolecule is associated with the electromagnetic energy absorbing species via a chemical bond. Instant claim 5 recites the composition of claim 1, where the biomolecules form a dimer via a chemical bond, the dimer associated with the electromagnetic energy absorbing species via the same chemical bond or via a different chemical bond. Instant claim 27 recites the composition of claim 24, where the biomolecule is associated with the susceptor via a chemical bond. Instant claim 28 recites the composition of claim 24, where the biomolecules form a dimer via a chemical bond, the dimer associated with the susceptor via the same chemical bond or via a different chemical bond.

Applicant submits **Pandey** et al do not disclose a biomolecule that is a biomaterial. **Pandey** et al do not disclose use of electromagnetic energy other than light energy. Nor do **Pandey** et al teach the energy absorbed is inductively applied. **Pandey** et al do not disclose use of a susceptor for absorbing the applied magnetic field, nor disclose a susceptor that

is a metal. As well, **Pandey** et al do not teach heating to cause a conformational change in the applied biomolecule. Rather **Pandey** et al teach a photosensitive pharmaceutical composition that is exposed to light and thereby activated to kill cells. Thus, the invention of **Pandey** et al teaches away from the instant invention because it does not use heat induced by application of a magnetic field but instead requires an activation process, exposure to light, that is not specified in the instant specification nor claimed as the instant invention.

As presented *supra* **Pandey** et al do not recite all the claim elements as set forth in the claims. Accordingly, in view of the arguments presented herein **Pandey** et al do not anticipate the instant invention and thus is not proper prior art. Therefore Applicant respectfully requests the standing rejection of claims 1-2, 4-5, 9-10, 12-14, 19-21, 24, 27-28, 32, and 35-36 under 35 U.S.C. §102(b) be withdrawn.

#### Claim rejections under 35 U.S.C. §103

Claims 23, 38, and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over **Pandey** et al., US Patent No: 5,093,349, in view of **Jori** et al US Patent No: 4,913,907. Applicant respectfully traverses the rejection.

The Examiner argues **Pandey** et al discloses all of the claimed embodiments except for the composition into a liposome. **Jori** et al demonstrates that it is well known to include the compounds of **Pandey** et al into injectable liposomes so they may be more compatible in tissues. Accordingly, the Examiner argues it would be obvious to one of ordinary skill in the art at the time the invention was made to place the **Pandey** et al composition within a liposome as taught by **Jori** et al so that **Pandey** et al composition exhibited these enhanced characteristics.

Instant claim 23 recites the composition of claim 1, further comprising a liposome, the composition incorporated therein. Instant claim 38 recites the composition of claim 24, where the biomolecule(s) comprise at least one protein, the composition further comprising a liposome where the protein(s) and the susceptor are incorporated therein. Instant Claim 39 recites the composition of claim 38, further comprising a pharmaceutical incorporated into the liposome.

As presented *supra*, Applicant submits **Pandey** et al do not disclose a biomolecule that is a biomaterial. **Pandey** et al do not disclose use of electromagnetic energy other than light energy. Nor do **Pandey** et al teach the energy absorbed is inductively applied.

**Pandey** et al do not disclose use of a susceptor for absorbing the applied magnetic field, nor disclose a susceptor that is a metal. As well, **Pandey** et al do not teach heating to cause a conformational change in the applied biomolecule. Thus **Pandey** et al do not teach or suggest all the claim limitations and do not provide motivation, suggestion, or a reasonable expectation of success to modify the **Pandey** et al invention of a photosensitive pharmaceutical composition that is exposed to light and to become activated to kill cells to the instant invention of a biomolecule that is a biomaterial and an electromagnetic energy absorbing species that is a metal susceptor which is heated by inductive application of the energy. Thus **Pandey** et al do not meet the criteria to establish obviousness. Therefore, **Pandey** et al does not render obvious the subject matter of the instant claims. The deficiencies of **Pandey** et al are not overcome by **Jori** et al.

Applicant submits **Jori** et al teach a therapeutic composition comprising one or more porphyrine compound incorporated into liposomes. The compound is administered to the patient and the affected body area is exposed a sufficient amount of light having a wavelength of 600nm to 950nm (**Jori** et al, Abstract).

Applicant submits the claimed invention teaches the incorporation of the biomolecule and the electromagnetic energy absorbing metal susceptor into a liposome. A liposome is not inherently responsive to induced heat generated by application of a magnetic field. Thus the teaching of **Jori** et al using liposomes with a photosensitive compound and the application of light does not provide motivation, suggestion or a reasonable expectation of success to modify the invention of **Jori** et al to the instant invention. Furthermore, combining the photosensitive compounds of **Pandey** et al with the liposomes of **Jori** et al still do not provide a suggestion, motivation or a reasonable expectation of success to modify to the instant invention.

Therefore, **Pandey** et al and **Jori** et al do not render obvious the subject matter of claims 23, and 38-39. Accordingly, in view of the arguments presented herein, Applicants respectfully requests the standing rejection of claims 23, and 38-39 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action, mailed November 28, 2007. Applicant submits the pending claims are now in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicant encloses a Petition for a Three Months Extension of

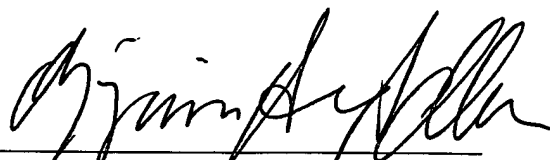


Time. Please charge the \$525 fee to the credit card identified on the enclosed Form PTO-2038. Only in the absence of Form PTO-2038, please debit any applicable fees from Deposit Account No. 07-1185 upon which the undersigned is allowed to draw.

Respectfully submitted,

Date:

My 08, 2008



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